

file history of the parent application and a copy of applicants' Claim for Convention Priority in that case is attached herewith. Therefore, applicants respectfully request the Examiner to acknowledge applicants' priority date of January 16, 1997 or contact the undersigned to clarify the Examiner's concern.

II. Rejection under 35 USC § 112, second paragraph

The Examiner rejects claims 21, 23 and 25 as being indefinite for reciting "bound" in part (d). In response, applicants have amended claim 25 by clarifying that binding occurs by way of a peptide bond. With this amendment, applicants do not acquiesce in the Examiner's rejection but merely explicitly clarify what is inherent to the invention. Accordingly, applicants request the Examiner to withdraw this rejection.

III. Rejections under 35 USC § 112, first paragraph

A. Questionable "Utility"

At pages 3-8 of the present Action, the Examiner rejects claims 21, 23 and 25 for the apparent reason that "...based on the state of the art, in the absence of experimental evidence, no one skilled in the art would accept the assertion that the claimed polypeptide could be used for treating prostate cancer metastasis." (page 7, lines 13-16). Applicants vigorously traverse this rejection.

First applicants point out that the claims in question do not recite methods of treating cancer. Secondly, the Examiner's rejection sounds like a utility rejection and the Examiner appears to concede this with reference to § 101 at page 8 under the "scope" rejection.

It is clear from the detailed description of the invention that applicants' nucleic acid construct can be designed for multiple purposes, one of which is in the treatment of tumors. The polypeptide encoded by such construct, which is the subject matter of this application, also has multiple purposes. The specification teaches the skilled artisan how to make the claimed polypeptide and how to use it. Although a degree of experimentation is necessary for such use, this experimentation is routine for the field of this invention. The Examiner's lengthy discussion about predictability in

cancer treatments is simply misplaced. And, with regard to the Examiner's concern about *in vivo* administration, the specification contemplates *ex vivo* administration, as well. See e.g. pages 44 and 45. The applications described in the specification rely upon well-known and well-accepted techniques. The law does not require that the results of an experiment be predictable. Rather, the law requires that the methods employed in such experimentation be reliable ones, *i.e.*, those that are accepted to the skilled artisan. The methods of using the claimed polypeptide described in the present application meet this requirement.

Applicants further direct the Examiner's attention to U.S. Patent No. 6,080,575, which is the parent of the present application and consequently shares the same specification as the present application. Claims in this patent are directed to the nucleic acid construct that encodes the presently claimed polypeptide. The Examiner in the parent case did not question the utility of the claimed nucleic acid constructs.

B. "Scope"

Applicants do not fully understand the Examiner's "scope" rejection. Nevertheless, in an effort to expedite examination only, applicants have amended claim 25 to recite "an amino acid sequence cleavable specifically by a protease which is released from a mammalian cell. The specification supports this amendment at page 10, lines 4-10. Also, a wide variety of proteases are released from the cell types which are indicated at page 10, line 17 through page 11, line 9. Such cells could be tumor cells but also could be many other mammalian cells, including for example, endothelial cells, macrophages, lymphocytes muscle cells, epithelial cells, glia cells, synovial cells and virus infected cells.

In view of the above, applicants respectfully request the Examiner to reconsider and withdraw the rejections under § 112.

S.N. 09/256,237

Atty. Dkt. No. 026083/0195



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CONCLUSION

Applicants respectfully request the Examiner to withdraw all pending rejections and allow claims 25, 21 and 23 to issue. Applicants also request reconsideration of the Examiner's refusal to rejoin claim 19 with claims 25, 21 and 23. Early notification of allowable subject matter is earnestly solicited.

TECH CENTER 1600/2900

Respectfully submitted,

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